



Howard Hughes Medical Institute
Research Laboratories

Richard H. Ebright, Ph.D.
Investigator

February 14, 2003

Centers for Disease Control and Prevention
National Center for Infectious Diseases
Select Agent Transfer Program
1600 Clifton Road NE., Mailstop E-79
Atlanta GA 30333

RE: Interim Final Rule for Possession, Use, and Transfer of Select Agents

Dear Colleagues:

I wish to submit the following additional comments on the Interim Final Rule for Possession, Use, and Transfer of Select Agents (prompted by the comments submitted on January 30, 2003 by the Department of Energy Joint Genome Institute; see <http://www.cdc.gov/od/sap/comments/03sar043.pdf>):

73.4, paragraph e (select agents--genetic elements, recombinant nucleic acids, and recombinant organisms)

and

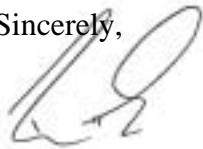
73.5, paragraph e (overlap select agents--genetic elements, recombinant nucleic acids, and recombinant organisms)

In section (2), "Nucleic acid (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section" should be replaced by "Nucleic acid (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section, or of any of the toxins produced by the select agents listed in paragraphs (a)-(c)."

The previous select-agent rule, 42 CFR 72.6, covered nucleic acids encoding toxins produced by select agents (as "genetic elements from organisms on Appendix A shown to produce or encode a factor associated with a disease"). It is essential that such nucleic acids--which readily can be introduced into exempt avirulent strains of listed agents, or into non-listed agents, to construct virulent agents--also be covered under new select-agent rule. [Indeed, this is so obviously, fundamentally essential that I did not notice the de-listing of these nucleic acids until I read the "Notice of Intent Not to Register" submitted on January 30, 2003 by the Department of Energy Joint Genome Institute (see <http://www.cdc.gov/od/sap/comments/03sar043.pdf>).]

I appreciate the opportunity to comment on the Interim Final Rule. Thank you in advance for your attention.

Sincerely,

A handwritten signature in black ink, appearing to read 'REBRIGHT', written in a cursive style.

Richard H. Ebright
Investigator, Howard Hughes Medical Institute
Laboratory Director, Waksman Institute
Professor of Chemistry, Rutgers University